DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration 9400 '01 MAR -1 A7:56

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of ivermectin injection for the treatment and control of various species of external and internal parasites in cattle, swine, reindeer, and American bison.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–228 that provides for use of Phoenectin™ (ivermectin) Injection for cattle and swine. The ANADA provides for use of a 1 percent solution of ivermectin, by subcutaneous injection, in cattle for the treatment and control of various species of gastrointestinal nematodes, lungworms, grubs, lice, and mites; in swine for the treatment and control of various species of gastrointestinal nematodes, lungworms, lice, and mites; in reindeer for the treatment and control of warbles; and in American bison for the treatment and control of grubs. The ANADA is approved as a generic copy of Merial Ltd.'s NADA 128–409 for Ivomec® (ivermectin) Injection.

cv012 ANADA 200-228 NFR-1

ANADA 200–228 is approved as of December 27, 2000, and the regulations are amended in 21 CFR 522.1192 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1192 is amended by revising paragraph (b) to read as follows:

§ 522.1192 Ivermectin injection.

* * * * *

(b) *Sponsors*. See No. 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section. See No. 059130 in § 510.600(c) of this chapter for use as in paragraphs (d)(2), (d)(3), (d)(4), and (d)(6) of this section.

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Dated: 2/12/01

February 12, 2001.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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